



Advances in Minimally Invasive Surgery for Small Hospitals. Translational medicine in surgery

Tiutiuca Razvan Calin^{1,2}, Nastase Puscasu Alina Ioana³, Roca Mihai⁴, Stoenescu Nicoleta⁵, Moscalu Mihaela², Scripcariu Dragos -Viorel^{2,3}, Bradea Costel², Lupascu Cristian²

¹ Iasi Military Hospital, ²University of Medicine and Pharmacy "Grigore T. Popa" Iasi, ³ Regional Institute of Oncology Iasi, ⁴University "Petre Andrei" Iasi, ⁵University „Alexandru Ioan Cuza" Iasi

Abstract. The concerns around hospitals' management, regardless of size and location, are all constructed around cost, quality and workforce (1). This would all suggest that smaller hospitals matter little in the delivery of general population healthcare at national level, larger organizations providing the dominant care. And yet, for many reasons, the role of small hospitals is not negligible. Alternative structures, policies and funding mechanisms, based on the evidence, are urgently needed to support them (2). Although some medical approaches are traditionally associated with large hospitals, they can also be successfully implemented for smaller units. This is also the case with minimally invasive treatment techniques. Minimally invasive surgery uses small incisions and specialized instruments to perform various procedures with less trauma and faster recovery than traditional open surgery. As a result, it is offering numerous benefits to patients, including reduced pain, bleeding, infection, scarring, shorter hospital stays, and improved cosmetic outcomes. Advanced procedures, traditionally associated with larger medical centers, can also be implemented in small hospitals expanding their surgical capabilities (1). This article discusses the benefits, challenges, and considerations for implementing these techniques in resource-limited settings. By adopting these advancements, small hospitals can enhance patient care, attract skilled surgeons, and strengthen their position in the healthcare landscape. Finally, also may prove benefits such as lower costs, higher efficiency, better outcomes and increased patient satisfaction. This approach rises some challenges for small hospitals, such as the need for adequate training, equipment, infrastructure and support. There may be difficulties in acquiring and maintaining specific devices, which are often expensive and complex. They may also lack qualified and experienced surgeons, nurses and technicians who can perform these procedures safely and effectively. Furthermore, it may require access to resources such as blood banks, intensive care units and referral centers in case of complications or emergencies.

Key word: Minimally Invasive Surgery, Small Hospitals, Translational medicine in surgery

Introduction

In the past, having surgery meant you were facing large incisions and long recovery times. But advancements in surgical techniques have helped surgeons see and fix things inside of your body without the need for invasive approaches (3). Minimally invasive surgery is a surgical procedure that causes little or no trauma or injury to the patient. It is done through small incisions using lasers, endoscopes, or laparoscopes. Laparoscopic surgery is a surgical technique that allows for the performance of surgical procedures with minimal damage to surrounding tissues. It involves the use of small

Corresponding author: Bradea Costel email: bradeacostel@yahoo.com

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incisions, specialized surgical instruments, and advanced` imaging technology to access and operate on internal structures. The laparoscope provides high-resolution images of the surgical site, allowing surgeons to visualize the internal structures on a video monitor. Compared with other procedures, those in this category involve reduced trauma, less bleeding, smaller amounts of anesthesia, less pain, shorter hospital stays, quicker return to normal activities and minimal scarring. Minimally invasive procedures limit the size of incisions needed, thereby reducing wound healing time, associated pain, and risk of infection (4).

Minimally invasive surgery can be used in various surgical specialties, including gynecology, urology, gastroenterology, orthopedics, and general surgery (3-5). Laparoscopic surgery has evolved significantly since its inception in the late 1980s. Initially, it was primarily used for diagnostic purposes, such as exploring the abdominal cavity to diagnose certain conditions. However, advancements in technology and surgical techniques have expanded its application to a wide range of procedures (6).

The first laparoscopic procedure in humans was performed by Kelling in 1901, who used a cystoscope to examine the peritoneal cavity of a dog and later of a human patient. The term laparoscopy was coined by Jacobaeus in 1910, who used it to diagnose tuberculous peritonitis. In the following decades, laparoscopy was mainly used for diagnostic purposes, until Palmer introduced the concept of operative laparoscopy in 1947 by performing tubal sterilization. However, it was not until the 1960s and 1980s that laparoscopy underwent a major transformation from a diagnostic tool to an independent surgical approach, thanks to the development of new instruments, techniques, and technologies. Some of the key figures in this period were Frangenheim, who introduced the automatic insufflator and the electrosurgical loop; Semm, who performed the first laparoscopic appendectomy and developed many instruments and devices for laparoscopy; and Mouret, who performed the first laparoscopic cholecystectomy. The first laparoscopic

cholecystectomy was performed in 1987, marking a major shift from traditional open surgery for this common procedure (6).

Laparoscopic surgery has since expanded to various surgical specialties and subspecialties, such as gynecology, urology, general surgery, bariatric surgery, colorectal surgery, hepatobiliary surgery, thoracic surgery, cardiac surgery, vascular surgery, and pediatric surgery (7).

Laparoscopic surgery has also been applied to treat various benign and malignant conditions, such as endometriosis, ovarian cysts, fibroids, ectopic pregnancy, pelvic organ prolapse, urinary incontinence, prostate cancer, kidney cancer, bladder cancer, colon cancer, rectal cancer, liver cancer, pancreatic cancer, lung cancer, esophageal cancer, gastric cancer, and cardiac valve diseases (7).

Laparoscopic surgery has also been influenced by the emergence of new technologies and innovations, such as single-incision laparoscopic surgery (SILS), natural orifice transluminal endoscopic surgery (NOTES), robot-assisted laparoscopic surgery (RALS), artificial intelligence (AI), and augmented reality (AR) (7, 8).

Numerous studies have demonstrated the benefits of laparoscopic surgery. For instance, a study by Liang et al. (2008) evaluated patient satisfaction, chronic pain, and functional status following laparoscopic ventral hernia repair. The authors found that improved patient outcomes and reduced chronic pain compared to open surgery. Markar et al. (2011) conducted a systematic review and meta-analysis comparing robotic and laparoscopic colorectal surgery. Their findings suggested that MIS techniques, including robotic surgery, had similar or better outcomes than traditional open surgery. Additionally, Joseph et al. (2005) explored the risk associated with the method in morbidly obese patients. They concluded that laparoscopic surgery carried a higher risk in this patient population, highlighting the need for careful patient selection and skilled surgical techniques (6). Overall, it represents a significant advancement in surgical approaches, offering patients numerous benefits and improved

outcomes. It continues to evolve with advancements in technology and technique, further enhancing its effectiveness and expanding its applications.

Importance of minimally invasive surgery for small hospitals

Taking these aspects into account, the method can be an important option for small hospitals because it offers many benefits to patients and hospital management. These benefits include reduced patient trauma, less postoperative pain, fewer operative and post-operative major complications, shortened hospital stay, faster recovery times, less scarring, less stress on the immune system, smaller incision, and for some procedures reduced operating time and reduced costs (9). The key reasons why laparoscopic surgery is important for small hospitals include improved patient satisfaction and outcomes and the fact that by reducing the length of hospital stays allows hospitals to accommodate more patients and optimize bed utilization. Also, small hospitals can provide more efficient healthcare services by reducing patient recovery times and increasing the number of patients they can treat. Also, compared to open surgeries, the procedure has been associated with lower rates of surgical site infections. The smaller incisions minimize the exposure of internal organs to external contaminants, reducing the risk of infection. For small hospitals with limited infection control resources, MIS can help in maintaining a safer surgical environment. While the initial investment in equipment and training for minimally invasive surgery can be substantial, it can lead to long-term cost savings for small hospitals. Reduced hospital stays, faster recovery, and lower complication rates can result in overall cost savings in the healthcare system (10-14).

Laparoscopic surgery continues to evolve. High-definition laparoscopic cameras, three-dimensional imaging, and fluorescence imaging techniques are being utilized to improve visualization during surgery, allowing for better identification of anatomical structures and precise surgical maneuvers. Today laparoscopic surgery is increasingly being used for complex

procedures that were traditionally performed through open surgery. Artificial intelligence is being explored to enhance laparoscopic surgery by providing real-time guidance, decision support, and automated assistance. AI algorithms can analyze laparoscopic images, predict surgical outcomes, and assist in surgical planning (15-19).

While larger hospitals may have a wider range of laparoscopic procedures available, small hospitals can still perform certain laparoscopic procedures effectively. Suitable laparoscopic procedures for small hospitals include: cholecystectomy, appendectomy, hernia repair, ovarian cystectomy, hysterectomy, Nissen fundoplication, colectomy, tubal ligation, biopsy.

Training and infrastructure requirements

Training in laparoscopic surgery requires a combination of theoretical knowledge, practical skills, and adequate infrastructure. Training requirements include knowledge, hands-on skills, mentored training and gradual progression. Surgeons need a thorough understanding of laparoscopic anatomy, physiology, and principles of laparoscopic surgery. They should be familiar with various laparoscopic instruments and equipment. Training programs typically include hands-on practice on laparoscopic simulators and training boxes. Surgeons need to develop skills in hand-eye coordination, instrument manipulation, camera control, and suturing techniques. It is crucial to receive training under the guidance of experienced laparoscopic surgeons. Mentorship programs, workshops, and proctoring sessions can provide valuable guidance and feedback during the learning process. Surgeons usually start with basic procedures and gradually advance to more complex surgeries as their skills improve. Stepwise training programs allow for a structured learning curve (10).

Infrastructure Requirements consists in operating room setup, trocars and instruments, the video system, energy sources and anesthesia support. The operating room should be equipped with specialized laparoscopic instruments, high-definition cameras, monitors, and insufflators for pneumoperitoneum (creation of a gas-filled abdominal cavity). It should also have appropriate lighting and video recording

capabilities. A variety of trocars (entry ports for instruments) and laparoscopic instruments such as graspers, scissors, dissectors, and staplers are needed for different procedures. These instruments should be of high quality and suitable for laparoscopic use. A high-resolution video system is essential for visualization during laparoscopic surgery. This includes a camera, light source, and high-definition monitors for the surgical team to view the procedure. Laparoscopic procedures may require energy sources for cutting, coagulating, and sealing tissues. Electrosurgical units or other energy devices should be available. Anesthesia equipment and techniques need to be adapted to the requirements of laparoscopic surgery, including patient positioning, management of pneumoperitoneum, and monitoring of the patient's vital signs (20-24).

Combining minimally invasive and traditional techniques. Hybrid Approaches

The combination of laparoscopy and traditional surgical techniques is often referred to as "hybrid surgery" or "laparoscopic-assisted surgery." This approach allows surgeons to benefit from the advantages of both techniques while minimizing the drawbacks. Hybrid surgery has been utilized in various surgical specialties, including general surgery, gynecology, urology, and colorectal surgery, among others. In colorectal surgery, a laparoscopic-assisted colectomy involves using laparoscopic techniques to mobilize the colon and perform much of the procedure. However, an additional larger incision is made to remove the specimen or create an anastomosis (reconnection) of the colon. This hybrid approach reduces the size of the incision compared to traditional open surgery while still allowing the surgeon to perform critical steps with direct visualization. In gynecology, a laparoscopic-assisted hysterectomy combines laparoscopy with an open approach. The surgeon uses laparoscopy to visualize and dissect the uterus and surrounding structures. Then a small incision is made in the vagina, allowing the uterus to be removed. In urology, laparoscopic-assisted nephrectomy involves using laparoscopic techniques to dissect and isolate the kidney, but a larger incision is

made to extract the kidney. This approach reduces trauma to the abdominal wall, improves postoperative pain control, and shortens hospital stay compared to open nephrectomy (25, 26). Hybrid techniques can be applied in various other procedures. The specific choice of approach depends on the surgeon's expertise, patient characteristics, and the complexity of the case (25-27).

Benefits for complex procedures in small hospitals

Performing complex procedures in small hospitals can present certain challenges due to limited resources and expertise. However, combining laparoscopy and traditional techniques in these settings can offer several benefits like reduced surgical trauma, less blood loss, and lower risk of postoperative complications, faster recovery, shorter hospital stays, and improved patient outcomes. Also, laparoscopy provides high-definition imaging and magnification, enabling surgeons to have a clear view of the surgical site. This enhanced visualization allows for precise dissection and identification of structures, particularly in complex procedures where anatomical landmarks may be challenging to identify. It also facilitates better control and manipulation of tissues during surgery. The use of laparoscopic instruments and techniques in combination with traditional approaches allows for precise and gentle tissue handling. This reduces the risk of tissue damage, improves postoperative healing, and may result in better functional outcomes for patients. Smaller incisions in laparoscopic-assisted procedures can help reduce the risk of surgical site infections. Infections are a significant concern in any surgical setting, and minimizing the size and number of incisions can contribute to better infection control, particularly in resource-limited settings (28, 30).

Patients may experience less pain, require fewer pain medications, and resume their daily activities sooner compared to traditional open surgery. This benefit can be especially crucial in small hospitals, where resources may be limited, and patient turnover needs to be efficient. It's important to note that the feasibility and success of complex procedures in small

hospitals depend on the availability of skilled surgeons, adequate infrastructure, and appropriate patient selection. Collaboration with larger centers, telemedicine support, and ongoing training and education can further enhance the outcomes (28-32).

Personal Experience

We discuss the strategy of a hospital with a capacity of less than 200 beds, of which 25 are for digestive surgery. The classification of the hospital by level of competence allows performing surgical interventions in the digestive sphere up to the level of complexity of major liver resections. The bordering organizational environment consists of large, highly competitive medical units with advanced equipment (including robotic surgery), well-trained surgical teams and intensive care services with advanced skills.

Until the diversification of the portfolio, the laparoscopic activity included cholecystectomy, appendectomy, ovarian cyst opeculectomy, inguinal hernia treatment, low-complexity herniations and varicocele treatment. Considering the extreme competitive environment in which the unit operates, we analyzed, elaborated and implemented a minimally invasive laparoscopic surgery development program adapted to the conditions of our service.

We evaluated the existing infrastructure, resources, and capabilities of the hospital regarding this project, and any gaps in equipment, staff expertise, or patient demand for minimally invasive procedures. We formed a team comprising surgeons, anesthesiologists, nurses, and administrators to oversee the development. This team will be responsible for creating strategies, implementing changes, and monitoring progress. We determine the specific areas of surgical specialization where laparoscopic techniques can have the most significant impact and considered factors such as patient demographics, prevalence of surgical conditions, and evaluated the potential cost savings associated, thinking about spitalization costs.

The preparation of the surgical activity began with the specialization of the medical staff

through courses to ensure a high level of competence for the doctors, specializations in liver and pancreatic surgery, as well as meetings and video presentations of the expected interventions with the staff in the operating room. Some doctors interested and motivated participated in high specialization training courses, workshops and conferences in laparoscopic and hepatobiliary surgery and other specialized in medical management. We invited a visiting expert to assist proctor surgeries.

The support staff was instructed to enhance knowledge and skills in assisting with these procedures. This include education on sterile technique, handling specialized instruments, and perioperative patient care.

Equipment included an intraoperative ultrasound system, the completion of laparoscopy instrument kits, the acquisition of vascular sealing systems and ultrasonic dissection and sealing with related peripherals, choledoscopy device. Laparoscopic mechanical suturing devices were envisioned.

We began collaboration with other hospitals, First Surgical Clinic from Sf Spiridon Hospital Iassy, and UMF Iassy, that have well-established similar programs. The operating team was formed by two senior surgeons, one with expertise in hepato-bilio-pancreatic surgery and training in laparoscopic surgery, and the second with a high level of laparoscopic expertise, university teaching staff. A junior specialist surgeon and a general surgery resident physician were co-opted. Anesthesia and intensive care was provided by doctors with over 20 years of expertise in the specialty.

During the first 6 months, we tried to approach a varied pathology, some complex cases, to strengthen the team and the functionality of the system.

Thus, a case with bilateral adnexectomy for benign ovarian tumors, 5 rectal neoplasia surgery, a right hemicolectomy, a left hemicolectomy, two cases of choledocho-duodenal anastomoses (one of the cases with concomitant choledochal lithiasis extraction), four cases of hiatal hernias with GERD, a case in which cholecystectomy and gastroenteroanastomosis were performed for

concomitant duodenal stenosis, a gastric partial resection for GIST tumour on the lesser curvature, a splenic cyst and a total hysterectomy with bilateral adnexectomy and transvaginal extraction of the surgical piece. In many cases postoperative recovery was rapid. Complications were rare and their management was easier to manage than if they were associated with open air surgery.

The cases of biliary surgery that were approached surgically (bilio-digestive anastomoses) were situations where endoscopic methods were contraindicated or impossible to perform.

We present for example, the case of a 73-year-old female patient with previous cholecystectomy, diagnosed with breast cancer in 2022 and recently with pancreatic neoplasm with duodenal invasion and secondary intense obstructive jaundice. Liver metastases of incert origin were present. After performing a computer tomography, IRM and upper digestive endoscopy with biopsy of duodenum (adenocarcinoma in filtration with a pancreato-biliary phenotype) we assessed the possibility of using a biliary stent. After the attempt to conduct stenting failed, and the possibility of percutaneous drainage was excluded by the interventional radiologist the patient was referred to the surgery unit so that a life-saving biliary drainage to be done. After laparoscopic exploration, we chose to perform a laparoscopic latero lateral choledochoduodenostomy (cholecystomized patient in the history). An episode of hepatic decompensation is noted and evidence of ascites increase flow is recorded of 3500-4000 ml/24 hours on the drain tube. The intensive therapy was aggressive and effective, and the absence of wide parietal incisions made the therapeutic approach easier. The patient was discharged on the 12th postoperative day with an improved general condition. We referred the case to the oncologist in order to initiate chemotherapy treatment. At 5 months, the patient was alive with a satisfactory quality of life.

The second situation is the case of a 69-year-old patient known with gastric neoplasm for which he benefited from gastric resection in 2018. In present he is hospitalized in our surgical clinic

with obstructive jaundice, cholestasis syndrome and moderate hepatocytolysis syndrome. After carefully evaluating the patient, we concluded the diagnosis of vesicular lithiasis and main biliary tract lithiasis. Considering the patient's previous history of gastric resection, we established the impossibility of inserting a biliary stent. The surgical laparoscopic intervention is decided. Cholecystectomy, choledochotomy, lavage of the common hepatic duct with calculus extraction and latero-lateral choledochoduodenostomy is performed. The postoperative evolution is favorable, with the resumption of digestive tolerability immediately after the surgical intervention. The patient is discharged on the 5th day after the operation, without complications. The imaging investigations performed at 3 and 6 months were within normal parameters.

The Nissen procedures were standard techniques and evolution with short postoperative stay in intensive care units and were discharged in the third postoperative day.

The splenic cyst was treated by laparoscopic operculectomy and drainage, thus avoiding splenectomy in a young patient.

Hybrid techniques, combinations of laparoscopic and open air techniques, were used in the case of transvaginal extraction of the total hysterectomy piece with bilateral adnexectomy which was performed laparoscopically guided, in the case of ileotransverso anastomosis after right hemicolectomy (performed manually through a mini laparotomy) and in the case of amputation of rectum, when the perineal sequence was conducted under laparoscopic guidance and restoration of the left iliac anus (performed before neoadjuvant radiochemotherapy) was also performed manually, using a technical variant that did not require laparotomy.

The tactic adopted regarding the follow-up of patients postoperatively required an extension of the hospitalization duration to accommodate the team with the techniques introduced, but incomparably shorter with the durations obtained in the same service for the same types of interventions in open surgery.

We appreciate antireflux surgery and colonic surgery as favorable directions for

development. Hepatobiliary and pancreatic surgery is feasible and requires skills of the operating and intensive care team, but is safely approachable.

The time required for **a surgeon to become skilled** in advanced laparoscopic techniques can vary depending on several factors, including the surgeon's prior experience, dedication to training, exposure to cases, and individual learning abilities. However, there is a general timeline that can provide an estimate. Surgeons typically acquire basic laparoscopic skills during their surgical residency or fellowship training. This involves learning basic laparoscopic techniques, instrument handling and camera navigation. Basic proficiency is usually achieved within 1-2 years of training. After obtaining basic laparoscopic skills, surgeons interested in advanced laparoscopic techniques undergo additional focused training. This can include attending specialized courses, workshops, and participating in proctorships with experienced laparoscopic surgeons. Advanced training may take an additional 1-2 years or more, depending on the intensity of training and the complexity of procedures being learned.

Hands-on experience is crucial for a surgeon to develop proficiency in advanced laparoscopic techniques. Regular exposure to laparoscopic cases, under the guidance of experienced laparoscopic surgeons, allows surgeons to refine their skills and gain confidence. The duration of this phase can vary but typically takes a few years, during which the surgeon gradually becomes more proficient. Even after achieving proficiency in advanced laparoscopic techniques, surgeons must engage in continuous professional development to stay updated on the latest advancements and refine their skills further. This involves attending conferences, participating in workshops, and staying connected with the laparoscopic surgical community. Professional growth and skill refinement in laparoscopic techniques continue throughout a surgeon's career. It is important to note that proficiency in laparoscopic techniques is a gradual process and can vary among individuals. Some surgeons may require more time and practice to become skilled, while others

may progress more quickly. Additionally, the complexity and diversity of advanced laparoscopic procedures can also impact the time required to master specific techniques. Ultimately, the journey to becoming skilled in advanced laparoscopic techniques is a continuous process that involves a combination of formal training, case experience, mentorship, and ongoing professional development.

The number of operations necessary for a surgeon to become skilled in advanced laparoscopic techniques can vary widely based on multiple factors, including the complexity of procedures, the surgeon's prior experience, the intensity of training, and individual learning abilities. While there is no fixed number, there are some general considerations. During residency or fellowship training, surgeons typically perform a range of basic laparoscopic procedures. The number of cases required to achieve basic proficiency varies but can range from 20 to 50 cases, depending on the program and individual progress. After acquiring basic skills, surgeons focus on advanced laparoscopic techniques. The number of cases needed to achieve proficiency in advanced procedures can vary widely. Surgeons may need to perform anywhere from 50 to several hundred cases, depending on the complexity and diversity of procedures being learned.

Case volume and variety is a crucial factor. Exposure to a diverse range of cases is crucial for skill development. For this reason we strive for the pathology approached to be very varied. Surgeons benefit from performing different procedures and encountering various scenarios to refine their techniques. The number of cases required to gain proficiency can depend on the variety and complexity of procedures encountered, but it is often recommended to aim for a minimum number of cases per procedure type (e.g., 20-30 cases for specific advanced laparoscopic procedures). It's important to note that these numbers are approximate and can vary based on individual learning curves, surgical practice environments, and the specific goals and requirements of the surgeon's training program. The focus should always be on achieving competence and proficiency rather than solely reaching a specific number of cases.

Ultimately, achieving proficiency in advanced laparoscopic techniques is a combination of hands-on experience, continuous learning, and ongoing professional development. The journey to becoming skilled is unique to each surgeon and depends on the individual's abilities, dedication, and exposure to suitable cases. Consequently we try to implement quality assurance and monitoring: first time at two months, next at 6 months and then after one year. At the end of the first two years, when the activity and experience will reach the first threshold of training mentioned in the literature, we will make the analysis for the tactics of the next period. In conclusion we will develop and establish quality improvement initiatives, regular audits, and peer review processes to ensure adherence to best practices and patient safety guidelines.

Continuously evaluating the effectiveness and efficiency of the program is assured by patients satisfaction questionnaires. We also seek feedback from surgeons, staff, and patients to identify areas for improvement, and adapt the program accordingly.

Concluding remarks

Small hospitals can offer a number of advantages and benefits. Small hospitals often have a smaller patient population, which allows medical staff to develop closer relationships with patients. This means doctors and nurses can provide more personalized care, learn more about patients' medical histories and preferences, and better respond to their needs. Large and busy hospitals can have long waiting times for consultation appointments or surgery. In small hospitals, waiting times can be significantly reduced and patients can get faster and more efficient medical care. Small hospitals are often more flexible and adaptable to specific community needs. These hospitals can consider and address local health problems, such as specific population conditions, maternal and child health services or elderly care. Small hospitals can provide a less intimidating and quieter atmosphere for patients. Because the number of patients is smaller, the environment is likely to be calmer and more personal. This can

help reduce patients' anxiety and an overall sense of comfort and safety.

Combining these advantages with those of providing medical services of a quality comparable to that of large centers is a beneficial direction for the development of this practice segment. The approach of advanced laparoscopic techniques at the level of such an institution proves to be a feasible project under the conditions of ensuring the necessary technologies, adequate training of the staff, collaboration with the academic environment and the application of translational medical practices.

The first impediment encountered was addressability of patients, which is relatively low at the level of small centers. This aspect becomes very important in the development strategy and requires correlation with other institutions, presentation of portfolios and additional information to patients. All this fact implies that the range of surgical interventions addressed should be as wide as possible. Also we intend to engage in knowledge sharing, joint research projects, and skill exchange programs to further enhance the expertise and reputation of the hospital's MIS program.

We will address patient education and awareness by developing patient education materials, including brochures, videos, and online resources, to inform patients about the benefits and availability of existing procedures. Promotion awareness through community outreach programs, seminars, and collaborations with primary care physicians we hope it will increase referrals.

This is a promising technique that can improve the quality of care and the efficiency of health services in small hospitals. However, it requires careful planning, preparation and implementation to ensure its success and sustainability. By following these strategies, small hospitals can overcome the barriers and embrace these opportunities for their patients and staff.

Declaration of conflict of interest. The authors state that there is no conflict of financial or non-financial interests with the data and information presented in the article. Patients signed a informed consent and agreed to

publication of data. The study was approved by the committee of ethics committee.

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